DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Pin-Point Care Corporation
Mr. Jeff M. Hathaway
President
N1723 Center Street
Lebanon, Wisconsin 53047

July 20, 2015

Re: K150088
Trade/Device Name: Evacore Fully Disposable Vacuum Assist Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 26, 2015
Received: June 26, 2015

Dear Mr. Hathaway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pin-Point Care

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150088

Device Name
Evacore Fully Disposable Vacuum Assist Biopsy Device

Indications for Use *(Describe)*
To obtain percutaneous core biopsy samples from soft tissue and tumors of such organs as the liver, spleen, kidney, prostate, lung, breast, and lymph nodes. When used for breast biopsy, the product is for diagnosis only.

The extent histological abnormality in breast tissue cannot be reliably determined from mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not guarantee the complete removal of the affected tissue. When the sampled abnormality is not benign, it is necessary that the tissue margins be examined to ensure that the area of suspicion (e.g., malignancy) has been completely removed using standard surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared:

30 December, 2014

510(k) Summary

(As required per 21 CFR: §807.92)

Evacore Fully Disposable Vacuum Assist Biopsy Device

I. Applicant Information:

Pin-Point Care Corporation
N1723 Center Street
Lebanon, WI 53047

II. Contact Person:

Jeff M. Hathaway
Phone Number.....(262)623-1149
Fax Number.....(262)806-7499
Email.....jeff.hathaway@pin-pointcare.com

III. Device Information:

Classification.....Class II
Trade Name.....Evacore Fully Disposable Vacuum Assist Biopsy Device
Common Name.....Biopsy Instrument
Classification Name.....Gastroenterology-Urology Biopsy Instrument (21 CFR 876.1075)
Panel.....78 Gastroenterology/Urology
Product Code.....KNW

IV. Predicate Device Information:

Manufacturer.....Hologic – Suros Surgical Systems
Device.....Celero Vacuum Assisted Spring Loaded Core Biopsy Device
510(k) Number.....K034021

V. Device Description:

The Evacore Fully Disposable Vacuum Assist Biopsy Device is a gamma sterilized, single-use percutaneous biopsy device. The working end of the device consist of a stainless steel outer needle with a lateral aperture for sample acquisition (sample aperture), a stainless steel inner cutting cannula with a sharp edge, and a solid stainless steel stylet located inside the cutting cannula. The handle of the device contains (2) release buttons, a reset handle for the vacuum generator (thumb), a reset handle for the cutting cannula (two fingers), and a needle hub to adjust the needle

aperture orientation based on the location of the lesion. When the release buttons are depressed (consecutively or concurrently) a vacuum is generated at the needle sample aperture drawing tissue into the needle, then the cutting cannula is activated automatically, traversing across the sample aperture dissevering the tissue sample. The solid stainless steel stylet prevents the tissue sample from migrating towards the handle once it has been separated from the patient. The device is then removed from the patient and reset via the reset handles allowing the tissue sample to be removed.

VI. Indications for Use:

The Evacore Fully Disposable Vacuum Assist Biopsy Device is a Biopsy Instrument as described under the provisions of 21 CFR §876.1075 and is medically prescribed to obtain percutaneous core biopsy samples from soft tissue and tumors of such organs as the liver, spleen, kidney, prostate, lung, breast, and lymph nodes. When used for breast biopsy, the product is for diagnosis only.

The extent histological abnormality in breast tissue cannot be reliably determined from mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not guarantee the complete removal of the affected tissue. When the sampled abnormality is not benign, it is necessary that the tissue margins be examined to ensure that the area of suspicion (e.g., malignancy) has been completely removed using standard surgical procedures.

VII. Device Comparison:

Note: Unless otherwise stated, the Device Comparison for the Evacore Fully Disposable Vacuum Assist Biopsy Device is for all noted needle lengths and gauges.

Predicate Device Comparison Table

Comparison	Predicate Device – (K034021) Vacuum Assisted Spring Loaded Core Biopsy Device	Evacore Fully Disposable Vacuum Assist Biopsy Device
Intended Use	To obtain percutaneous core biopsy samples from soft tissue and tumors of such organs as the liver, spleen, kidney, prostate, lung, breast, and lymph nodes. When used for breast biopsy, the product is for diagnosis only.	Same
Target Population	Patients with suspicious soft tissue lesion(s)	Same
Product Code	KNW	Same
Outer Needle Diameter(s)	12 Guage	7, 11, and 14 Guage

Needle Length	≈123mm	115mm and 145mm
Number of samples	Unknown	16 samples
Method of Device Insertion	Working end of the device introduced without or with coaxial introducer	Same
Method of Tissue Collection	Insert the needle in the correct position, activate the device and wait for the device to finish cycling (automatic), remove the device from the patient, reset the device and manuallly extract the tissue sample.	Same
Optimal Sample Notch Length	22mm	19mm
Core Type	Partial Diameter	Full Diameter
Weight	135g	95g, 84g, and 79g (145mm needle length)
Selectable Sample Length	No	Yes (19mm or 11mm length)
Echogenic Needle Description: Used for enhancing ultrsound imaging.	Yes	Yes
Disposable Device	Fully disposable single patient use	Same
Device Sterility	Gamma Sterilization	Same
Sterile Barrier	Thermoformed tray with heat sealed Tyvek™ cover	Same
Shelf Life	3 years	Same
Electrical Safety	The device operates on mechanical principles only. Therefore, the device has no electrical components	Same
Method of Tissue Dissection	Cutting cannula advances across tissue aperture	Same
Mechanics of action	Automatic	Same
Needle Advancement/ Penetration Depth	25mm	N/A

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Mode of Action	Single puncture and sample, or single puncture and multiple samples with introducer	Same
Non-Contact Materials	Colored polymer housings with metal springs as the energy source	Same
Patient Contact Materials	300 Series Stainless Steel	Same
Vacuum Energy Source	Spring operated vacuum generator	Same
Cutting Cannula Energy Source	Spring operated cutting cannula	Same
Dual interlocks (manual) for vacuum generator release	No	Yes
Dual interlocks (automatic) for cutting cannula release	No	Yes
Rotating Cutting Cannula	No	Yes
Manual reset of the device	Yes	Yes
Hand-Held Procedure	Yes	Yes
Location Used	Physician's Office or O.R.	Same
Prescription vs. O.T.C.	Prescription	Same
Performance	Equivalency to white paper performance data	Bench test equivalency
Method of placement	CT/Ultrasound/Fluoroscopy/ Manual	Same

VIII. Non-Clinical Performance Data:

The Evacore Fully Disposable Vacuum Assist Biopsy Device was performance tested using empirical testing.

Summary of Non-Clinical Performance Data

Risk	Test Method	Acceptance Criteria	Results
7 gauge 115mm & 145mm needle length tissue sample size is inadequate	Simulated and supported with bench testing	Average volume of a sample > .105cm³	**PASS**
11 gauge 115mm & 145mm needle length tissue sample size is inadequate	Simulated and supported with bench testing	Average volume of a samples >.033cm³	**PASS**
14 gauge 115mm & 145mm needle length tissue sample size is inadequate	Simulated and supported with bench testing	Average mass of 8 samples > .018cm³	**PASS**

IX. Substantial Equivalency:

The flow chart shown below is a duplicate of the one that can be found in "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" in "Appendix A. 510(k) Decision-Making Flowchart". The pathway illustrates how the Evacore Fully Disposable Vacuum Assist Biopsy Device is substantially equivalent to the legally marketed predicate device.

The Predicate Device Comparison Table demonstrates that the Evacore Fully Disposable Vacuum Assist Biopsy Device has the same technological characteristics as the predicate device in terms of but not limited to, intended use, energy source, operating principals, optimal sample notch length, target population, device sterility, and method of tissue collection.

Conclusion:

Based on the Non-Clinical Performance Data provided in this summary, the Evacore Fully Disposable Vacuum Assist Biopsy Device has been shown to be substantially equivalent to the predicate device.

Note: See following page for flow chart.